

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION**

NATURAL ALTERNATIVES)	
INTERNATIONAL, INC.,)	
)	
Plaintiff,)	Civil Action No.: 4:11-cv-04511
v.)	
)	
WOODBOLT DISTRIBUTION, LLC,)	
also known as Cellucor;)	
F.H.G. CORPORATION,)	
d/b/a Integrity Nutraceuticals;)	
VITAQUEST INTERNATIONAL, INC.,)	
d/b/a Garden State Nutritionals,)	
)	
Defendants)	

**DEFENDANT WOODBOLT'S MOTION FOR SUMMARY JUDGMENT
OF PATENT INVALIDITY OF
PLAINTIFF'S U.S. PATENTS NOS. 8,067,381 AND 8,129,422**

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Introduction

Defendant, Woodbolt Distribution, LLC (“Woodbolt”) files this Motion for Summary Judgment of Patent Invalidity of Plaintiff’s U.S. Patent No, 8,067,381 (“‘381 Patent”) and U.S. Patent No. 8,129,422 (“‘422 Patent”), pursuant to the Court’s Order dated July 24, 2012 (D.I. 47).

Status of Woodbolt’s Reexamination Request

On July 26, 2012, the USPTO issued an Order Granting Woodbolt’s Request for *Inter Partes* Reexamination of the ‘381 Patent and an Office Action which rejected all of the ‘381 Patent claims based on prior art upon which Woodbolt relies in this motion.

Summary of Argument**A. The ‘381 and ‘422 Patents Relate to Well-Known Beta-Alanine Compositions**

The ‘381 and ‘422 Patents of plaintiff, Natural Alternatives International, Inc. (“NAI”), are directed to compositions containing beta-alanine for use in human dietary supplements.

Beta-alanine is a common, naturally-occurring amino acid found in the human body and in natural foods such as chicken. Its properties and role in mammalian and specifically human physiological processes have been studied for a half century or more and it has been commercially available for decades. Because beta-alanine is naturally occurring and its roles well known for decades, any purported novelty of the ‘381 and ‘422 Patent claims is premised on the use of beta-alanine in human dietary *food supplements*.

As described in detail below, many prior art references, including scientific publications and patents not considered by the United States Patent and Trademark Office (“USPTO”) during examination of the patent applications for these two patents, disclose the use of beta-alanine-containing compositions as human dietary food supplements. One such prior art patent is NAI’s own prior patent.

In this motion Woodbolt will demonstrate that all of the claims of the ‘381 Patent¹ and ‘422 Patent² are invalid under 35 U.S.C. §§ 102 and 103, because multiple prior art publications and patents disclose and render obvious the alleged inventions of the ‘381 and ‘422 Patents. With minor exception, none of these prior art publications and patents was of record during the prosecution of the ‘381 and ‘422 Patents. These new prior art references are more relevant than the prior art considered by the USPTO during examination. Accordingly, the burden of establishing invalidity is more easily met.

B. The USPTO’s Grant of Woodbolt’s Reexamination Request and Office Action Confirms That NAI’s Composition Containing Beta-Alanine is Well-Known

On May 31, 2012, Woodbolt filed a Request for *Inter Partes* Reexamination of the ‘381 Patent (“‘381 Request”) setting forth the same bases for invalidating the ‘381 Patent included in this motion.³ On July 26, 2012, the USPTO issued an Order Granting Request for Inter Partes Reexamination of the ‘381 Patent (“‘381 Reexam Order”) which adopts many of the bases for invalidity set forth in Woodbolt’s ‘381 Request, including the most important of those bases. The ‘381 Reexam Order states, with respect to each claim, that “...the examiner **agrees** that there is a reasonable likelihood that the Requester will prevail [against that claim]...” (emphasis original). The USPTO also issued an Office Action (“‘381 Office Action”) rejecting each claim of the ‘381 Patent on those bases.⁴

Most significantly, the ‘381 Office Action rejects *all* of the claims of the ‘381 Patent as anticipated by NAI’s own prior U.S. Patent No. 5,965,596 issued October 12, 1999 (“‘596 Patent”). The ‘381 Patent is the seventh patent to issue in a family of patents first filed in 1997. Although the ‘381 Patent purports to claim the 1997 filing date of the ‘596 Patent via a chain of priority claims in

¹ A copy of the ‘381 Patent is attached as Exhibit 1.

² A copy of the ‘422 Patent is attached as Exhibit 2.

³ A copy of the ‘381 Request including Exhibits is attached as Exhibit 3.

⁴ A copy of the ‘381 Reexam Order and the ‘381 Office Action are attached as Exhibit 4.

the seven virtually identical applications filed from 1997 to 2011, the USPTO agreed with Woodbolt that in the fifth application in the series, NAI had broken the chain by disclaiming the priority of the '596 Patent. The USPTO agreed with Woodbolt that the consequence of that disclaimer was that the fifth application and its successors were entitled only to a priority date of April 10, 2003. The '596 Patent, issued in 1999, discloses the "inventions" of the '381 Patent and thus invalidates all the claims of the '381 Patent.

On July 19, 2012 Woodbolt filed a Request for Inter Partes Reexamination of the '422 Patent ("422 Request") setting forth the same bases for invalidating the '422 Patent included in this motion.⁵ The '422 Patent merely claims a method for using the compositions containing beta-alanine claimed in the '381 Patent, as a food supplement. The methods of use include ingesting the compositions. Because the '422 Patent merely claims a method for using the '381 Patent composition, has the same title, specification, and drawings as the '381 Patent and has a purported claim to priority identical in all material respects to that of the '381 Patent, it is virtually certain that the USPTO will order a reexamination of the '422 Patent and reject the claims of the '422 Patent as it did in the '381 Reexam Order and Office Action. Based on the date of the '381 Reexam Order and Office Action, a '422 Reexam Order and Office Action are expected in September, 2012.

In view of the showing of invalidity by Woodbolt in this motion, the '381 Request and the '381 Reexam Order and Office Action, the '381 and '422 Patents should be found invalid.

**Standard For Summary Judgment Patent Invalidity,
And Novelty and Unobviousness Requirements for Patentability**

**A. Summary Judgment is Appropriate in Patent Cases
Where There is No Disputed Issue of Material Fact**

Summary judgment is governed by Rule 56, FRCP, and is proper if there is no genuine issue as to any material fact. Summary judgment is as appropriate in a patent case as in any other." *See*,

⁵ A copy of the '422 Request including Exhibits is attached as Exhibit 5.

e.g., Avia Group Int'l., Inc. v. L.A. Gear California, Inc., 853 F. 2d 1557, 1561 (Fed. Cir. 1988).

“[T]he salutary purposes of the grant of summary judgment under Fed. R. Civ. P. 56 is without question intended to be effectuated in patent litigation as in any other type of suit and in accordance with the same standard.” *Union Carbide Corp. v. American Can Co.*, 724 F. 2d 1567, 1571 (Fed. Cir. 1984) (footnote omitted); *see also Brenner v. United States*, 773 F. 2d 306, 307 (Fed. Cir. 1985).

B. To Be Patentable, a Patent Claim Must Describe Something Novel and Unobvious

1. Novelty Requirement

A patent claim is invalid if the claim does not satisfy the “novelty” requirement that the claimed subject matter be “novel” or “new” over the prior art (35 U.S.C. §102). A claim is invalid for lack of novelty if each element of the claim is found, either expressly or inherently, in a single prior art reference. *MEHL/Biophile Int'l. Corp. v. Milgraum*, 192 F. 3d 1365 (Fed. Cir. 1999).

Determining whether prior art renders a patent claim invalid for lack of novelty involves determining whether the requirements and limitations in the claims are found in the prior art. If the prior art disclosure falls within the literal scope of the claim, then the prior art destroys novelty of the claim. Stated another way, “that which infringes later, anticipates [destroys novelty] if earlier”. *Polaroid Corp. v. Eastman Kodak Co.*, 789 F. 2d 1556, 1573 (Fed Cir. 1986) (citing *Peters v. Active Mfg. Co.*, 129 U.S. 530, 537 (1889)). The prior art need only disclose a single structure or example which falls within the scope of the claim to defeat novelty.

A prior art reference which does not expressly disclose each feature of the claims still anticipates the claim if the missing claim feature is inherent, i.e., *necessarily present* or the result is *inevitable*, in the single prior art reference. *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 74 USPQ 2d 1398, 1407 (Fed. Cir. 2005) (Inherent anticipation found where prior art process *necessarily resulted* in production of claimed compound); *In re Montgomery*, 677 F.3d 1375, 1381 (Fed. Cir. 2012) (Inherent anticipation of a stroke treatment method found where

prior art compound would *inevitably* be efficacious in treating stroke). Moreover, inherent anticipation does not even require that a person of ordinary skill in the art recognize the inherent disclosure in the prior art at the time of the prior work. *SmithKline*, at 1407.

2. Unobviousness Requirement

To be patentable, in addition to satisfying “novelty”, claims must also be “unobvious” over the prior art. (35 U.S.C. §103) A claimed invention is obvious if one of ordinary skill in the art would have been able to arrive at the claimed invention by: combining prior elements in the same field of endeavor according to known methods to yield predictable results; or choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success (“obvious to try”); or following some teaching, suggestion, or motivation to modify or combine prior art reference teachings either from the prior art, their own experiences, or the nature of the problem posed. *KSR Intl. Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007); MPEP §2141.

C. Prior Art Not Considered By the USPTO Makes Invalidity Easier to Meet

One or more material prior art references that were not before the USPTO may make the standard of proving invalidity easier to meet. *Microsoft Corp. v. i4i Ltd. Partnership*, 131 S.Ct. 2238, 2251 (2011) (“Simply put, if the PTO did not have all the material facts before it [when deciding to issue the patent], its considered judgment [to issue the patent] may lose considerable force. And, concomitantly, the challenger’s burden to persuade the jury of the merits of the invalidity defense by clear and convincing evidence may be easier to sustain.”)

The '381 and '422 Patents Are Invalid Because All the Claims Are Anticipated Or Rendered Obvious By Prior Art Not Considered by the USPTO

A. Construction of the Claims of the '381 and '422 Patents

1. The '381 Claims

Claim 1 of the '381 Patent states:

1. A human dietary supplement comprising at least one of:
 an amino acid wherein said amino acid is beta-alanine that is not part of a dipeptide, polypeptide or oligopeptide;
 an ester of beta-alanine that is not part of a dipeptide, polypeptide or oligopeptide;
 an amide of beta-alanine that is not part of a dipeptide, polypeptide or oligopeptide.
 Claim 1 contains in its preamble the term "human dietary supplement." In the '381

Reexam Order the USPTO found that this term had no effect on the scope of the claim.⁶ That same construction was adopted in 2011 by the Delaware Court in a 2009 action on the first three NAI patents within the family which contained the same preamble term.⁷

The consequence of adhering to the construction of the claim by the USPTO in the '381 Reexam Order and by Judge Sleet in the Markman Order is that the claims of the '381 Patent are subject to invalidation over *any* published prior art composition containing beta-alanine used for *any* purpose. For example, claim 1 of the '381 Patent would be invalid over DeLacharriere, U.S. Patents Nos. 5,976,559 and 5,869,068, which disclose compositions containing beta-alanine for use as a skin cream to treat wrinkles.⁸

⁶ In the present claim 1 the recitation "a human dietary supplement", is not construed to be a limitation since it states the purpose or intended use of the composition...Thus, any prior art composition containing beta-alanine, even if *not* disclosed for use as a "human dietary supplement," is anticipating prior art to claims of the '381 Patent, because "human dietary supplement" is only in the claim preamble. Exhibit 4, '381 Reexam Order, p. 6-7.

⁷ In 2009, in an action styled NAI v. Vital Pharmaceuticals, Inc. (D.Del., C.A. No. 09-626), Chief Judge Gregory M. Sleet issued an Order Construing the Terms of U.S. Patent Nos. 5,965,596; 6,172,098; and 6,426,361 ("Markman Order"). A copy of the Markman Order dated May 31, 2009 is attached as Exhibit 6. Chief Judge Sleet ruled that the term "dietary supplement" was not a claim limitation requiring construction, but rather merely a statement of intended use and had not been used to distinguish the prior art. See footnote 2 of the Markman Order.

⁸ See Exhibit 3, '381 Request, pages 22-24 and Exhibit L and Exhibit 4, '381 Office Action, Ground #5, p. 11.

In the absence of a Markman proceeding in this action to construe the terms of the claims of the '381 and '422 Patents, the claim constructions adopted by Judge Sleet and by the USPTO should be adopted here. Nevertheless, to simplify the issues in the instant motion, Woodbolt agrees –for the purposes of this motion only – to consider the term “dietary supplement” to be a claim limitation, and further agrees – for the purposes of this motion only – to give the preamble term “dietary supplement” the meaning given to it by NAI during the prosecution of the '381 and '422 Patents.⁹ There NAI stated:

“By dietary supplements the Applicant means an addition to the diet in a pill, capsule, tablet, powder, or liquid form, which is not a natural or conventional food, and which effectively increases the function of tissues when consumed... To be clear, the term ‘dietary supplement’, as claimed, does not encompass, and does not mean, a natural or conventional food, such as chicken or chicken broth, for example.”¹⁰

In the Markman Order Judge Sleet construed the several chemical terms e.g. “beta-alanine”, “L-histidine” and all other terms believed to be relevant to this motion, as having their “...plain and ordinary...” meanings, and Woodbolt agrees that for the purposes of this motion the terms of the claims of the '381 and '422 Patents have those meanings.

Independent claim 1 of the '381 Patent has a preamble ending with the open-ended term “comprising.” As such, for purposes of invalidity, prior art which discloses a supplement having the required features of the claims will anticipate or render the claim invalid for lack of novelty, even if the prior art supplement has other components. *See Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1318 (Fed. Cir. 2009) (transitional “comprising” creates an open-ended claim which is anticipated by prior art even if the prior art has additional elements).

⁹ In the event this motion is denied, Woodbolt respectfully reserves its right to seek such alternative constructions as may be warranted.

¹⁰ Preliminary Amendment dated August 22, 2011 in Application Ser. No. 13/215,073 which issued as the '381 Patent, Exhibit 7 and Amendment dated October 11, 2011 in Application Ser. No. 12/806,356 which issued as the '422 Patent, Exhibit 8.

Also, claim 1 recites three alternative forms of the amino acid. It can be *beta-alanine*, or an *ester* of *beta-alanine*, or an *amide* of *beta alanine*. The prior art on which Woodbolt relies in this motion, and which it presented in the ‘381 Request and ‘422 Request, discloses the simple amino acid *beta-alanine*, not an *ester* or *amide* of beta-alanine. Thus, for simplicity in the invalidity analysis in this motion, one can simply ignore the other two variants, an *ester* or *amide* of beta-alanine, because a prior art disclosure of beta-alanine alone will invalidate the claims. *See Medichem, S.A. v. Rolabo, S.L.*, 353 F. 3d 928, 934-35 (Fed. Cir 2003) (“[i]t is ... an elementary principle of patent law that when ... a claim covers several compositions, the claim is “anticipated” if one of them is in the prior art.”) (quoting *Titanium Metals, Corp. v. Banner*, 778 F. 2d 775, 782 (Fed. Cir. 1985).

Claim 1 also states the qualifier that the beta-alanine “is not part of a dipeptide, polypeptide or oligopeptide”. That limitation was introduced by NAI into the claims of the applications which issued as the ‘381 and ‘422 Patents after the Markman Order which effectively invalidated similar claims which did not have that limitation. So the language “not part of ...” simply means that the beta-alanine in the claimed composition is in the form of a single amino acid and is not a dipeptide as in the three earlier related patents of the family in the Delaware action.

In view of the above and for the purposes of the invalidity analysis in the present motion, claim 1 of the ‘381 Patent can be rewritten simply as:

1. A human dietary supplement comprising...
beta-alanine [the simple amino acid, unbonded to a different amino acid]

2. The ‘422 Claims

Claims 12-19, only, of the ‘422 Patent are discussed below because they claim the use of beta-alanine-containing supplements by humans. Claims 1-11 are limited to non-human

subjects. Claims 12-19 were the only claims asserted in NAI's Motion for Preliminary Injunction (D.I. 14-1)

Claim 12 of the '422 Patent states:

12. A method to avoid or delay the onset of muscular fatigue in a subject, comprising:
- a) providing to the subject an amount of an amino acid to blood or blood plasma effective to increase beta-alanylhistidine dipeptide synthesis in muscle tissue, wherein said amino acid is at least one of:
 - i) beta-alanine that is not part of a dipeptide, polypeptide or oligopeptide;
 - ii) an ester of beta-alanine that is not part of a dipeptide, polypeptide or oligopeptide; or
 - iii) an amide of beta-alanine that is not part of a dipeptide, polypeptide or oligopeptide;
 and
 - b) exposing the muscle tissue to the blood or blood plasma, whereby the concentration of beta-alanylhistidine is increased in the muscle tissue, thereby avoiding or delaying the onset of muscular fatigue,
- wherein the amino acid is provided as a dietary supplement, and
wherein the subject is not a horse.

Claim 12 merely recites the use of beta-alanine as a dietary supplement. It too can be simplified for the purposes of this motion in the same way as discussed above for claim 1 of the '381 Patent. Reduced to its basic elements, claim 12 claims nothing more than the use of the composition, e.g. by ingesting it.

Claim 12 includes redundant or unneeded language, because it merely recites the inevitable results which occur when providing beta-alanine to a subject. When the subject ingests the dietary supplement, the beta-alanine will always, necessarily and inevitably, by well understood metabolic and physiological processes, pass from the gut into the blood, and the beta-alanine in the blood will inevitably reach the muscle tissue.¹¹ There the absorbed beta-alanine will inevitably combine with L-histidine already in the muscle tissue to form the beta-alanyl-histidine dipeptide.¹² Beta-alanyl-histidine dipeptide, also known as carnosine, has been understood for decades to avoid or delay the

¹¹ Hama, T., *J. Nutr. Sci. Vitaminol* **22**, 147-157, 1976, Exhibit 9 which reports that beta-alanine will accumulate in the gastrocnemius (calf) muscle where it is used for biosynthesis of beta-alanyl peptides such as beta-alanyl-histidine dipeptide (carnosine).

¹² Asatoor, A., *Gut*, 11, 380 (1970) ("Asatoor") p. 19-20 and Exhibit J to '381 Request, Exhibit 3.

onset of muscle fatigue in animal and human subjects.¹³ Thus, the result of ingesting beta-alanine necessarily increases the concentration of beta-alanyl-histidine (carnosine) in the muscle tissue to thereby inevitably avoid or delay the onset of fatigue. None of these inevitable steps and processes was “invented” by NAI and should not be considered as part of the claimed method. As will be discussed below, the USPTO in the ‘381 Office Action has determined that similar language in claims 13-14 of the ‘381 Patent merely states an inherent function of the composition.

Claim 12 of the ‘422 Patent can accordingly be simplified for purposes of this motion as follows:

12. A method comprising
providing ... amino acid to the subject..., wherein said amino acid is ...
beta-alanine [in its single amino acid form, unbonded to a different amino acid]
...
...wherein the beta alanine is provided as a dietary supplement, and
wherein the subject is not a horse.

Similar to the simplified claim 1 of the ‘381 Patent, the simplified claim 12 of the ‘422 Patent boils down to providing to a subject a dietary supplement containing the single amino acid beta-alanine.

Thus, prior art which discloses beta-alanine used as a dietary supplement, will invalidate the independent claims and other claims of both the ‘381 and ‘422 Patents, as will be discussed below.

¹³ European Patent Application Publication No. 0 449 787 A2 (March 19, 1991) (Applicant: Setra S.r.L) (“Setra”), Exhibit Q to ‘381 Request, Exhibit 3.

B. Beta-alanine is a Well Known Naturally Occurring Amino Acid

Beta-alanine (also known as β -alanine) and its preparation and availability have been known for decades.¹⁴ It can be purchased from many chemical companies. It has also been used in food products.¹⁵ Accordingly, beta-alanine is a well-known and studied amino acid decades before NAI's '381 and '422 Patents were filed.

Beta-alanine is one of the constituents of carnosine (beta-alanyl-L-histidine), the other being L-histidine. Carnosine was discovered to be a naturally occurring dipeptide found in muscle in 1900, and in 1911 it was found that carnosine was formed from beta-alanine and L-histidine.

C. Many Prior Art References Disclose the Claimed Inventions of the '381 and '422 Patents

The Patent Statute, 35 U.S.C. § 1, *et. seq.*, sets forth conditions for patentability, including a “novelty” requirement that the claimed invention must not be “...patented or disclosed in a printed publication in this or a foreign country...more than one year prior to the date of the application for patent in the United States, ...”¹⁶

The '381 and '422 Patents each have purported claims to priority, i.e. they claim the effective filing date (U.S. priority of August 12, 1997 and foreign priority of August 12, 1996) of the earliest-filed application in the family relating to compositions for use as dietary supplements and methods for using those compositions. As discussed in Section D below, these purported claims to priority were misrepresentations to the USPTO and to the public, and were advanced by

¹⁴ The Merck Index, Tenth Edition 1983, Merck & Co., Inc., Rahway, NJ; U.S. Patent Nos. 2,334,163; 2,336,067; 2,364,538; 2,416,630; 2,734,081; and 2,734,081 disclosing methods of preparing and isolating beta-alanine, Exhibit 10.

¹⁵ French Patent Application No. 2659013 with English (machine) translation (p. 2), and U.S. Patent Nos. Re 30,370 (col. 12, lines 19-39) and 3,966,988 (col. 1, lines 9-27 and col. 6, lines 25-68), Exhibit 11.

¹⁶ 35 U.S.C. §102(b)

NAI to mislead the USPTO of a false priority claim, and avoid a rejection of the claims of the '381 and '422 Patents over NAI's own '596 Patent.¹⁷

Nevertheless, solely for the purposes of this Section C of this motion, because the prior art is dated even before NAI's purported priority date, Woodbolt need not assert that NAI's purported claims to priority are defective. Any patent or publication prior to August 12, 1996 (NAI's foreign priority date) disclosing the claimed invention will anticipate the claims of the '381 and '422 Patents and render them invalid.

The claims of the '381 Patent are all directed to a human dietary supplement. The relevant prior art, therefore, includes any reference disclosing a human dietary supplement containing beta-alanine which is not a natural or conventional food. The claims of the '422 Patent are all directed to methods for delaying the onset of muscular (sic) fatigue by providing the supplement to a subject. The step of ingesting the supplement will necessarily introduce the beta-alanine supplement to blood or blood plasma, expose the muscle tissues of the subject to the blood or blood plasma and increase beta-alanyl-histidine (carnosine) synthesis in muscle tissue. The claimed method includes any method of providing beta-alanine to a human subject, which will necessarily result in beta-alanine entering the blood stream and then passing into the muscle tissues. The methods of providing beta-alanine to the subject include ingesting the supplement (claim 17) and infusing the supplement (claim 18).

The only step of the claimed method that the prior art needs to show to invalidate the claims of the '422 Patent is the step of providing (ingesting or infusing) a supplement containing beta-alanine. All other "steps" in the claimed method, after ingesting or infusing the composition, will

¹⁷ The USPTO agrees that the claims to priority are defective and that the effective filing date of the '381 Patent is April 10, 2003. See '381 Reexam Order, Issue #1, p. 7, and '381 Official Action, Ground #1, p. 7, Exhibit 4.

inevitably occur and will necessarily follow, and are thus inherent in human metabolic and physiological functions.

The prior art references are discussed below.¹⁸

Asatoor

Claims 1, 5, 10, 13 and 14 of the '381 Patent are anticipated under 35 U.S.C. § 102(b) by Asatoor (1970).¹⁹ Asatoor was studying the intestinal absorption of beta-alanine and L-histidine in humans. The publication discloses experiments in which five human test subjects ingested a mixture of beta-alanine and L-histidine dissolved in 500 ml of water.

Asatoor thus discloses a "human dietary supplement," which is not a natural or conventional food such as chicken or chicken broth, comprising "beta-alanine that is not part of a dipeptide, polypeptide or oligopeptide", according to claim 1. Claim 5 is anticipated because the Asatoor supplement contains L-histidine; claim 10 because the supplement is in liquid form; claims 13 and 14 because they merely recite the inherent effect of the composition when ingested.

Claims 12, 13, 17 and 19 of the '422 Patent are likewise anticipated by Asatoor. Once ingested by the human subject, the beta-alanine will necessarily be absorbed into the blood stream and from the blood stream into the subject's muscle tissue, and thus will inherently and necessarily increase beta-alanyl-histidine dipeptide synthesis in the muscle tissue. The result will necessarily avoid or delay onset of muscular fatigue. Claim 13 is anticipated because the dietary supplement ingested includes L-histidine; claim 17 because the method of administration was by ingestion; and claim 19 because the test subjects were human beings.

¹⁸ Claim charts showing all of the claims of the '381 and '422 Patents and the prior art references disclosing these claims are set forth in Exhibit 12.

¹⁹ Asatoor, p. 19-20 of Exhibit 3 and Exhibit J to Exhibit 3.

Gardner

Claims 1, 2, 3, 4, 5, 7, 10, 13 and 14 of the '381 Patent are anticipated under 35 U.S. C. § 102(b) by Gardner (1991).²⁰ Gardner discloses an experiment in which a human subject ingested a "test meal" comprising beta-alanine and histidine in syrup. Gardner thus discloses a "human dietary supplement" which is not a natural or conventional food, comprising "beta-alanine that is not part of a dipeptide, polypeptide or oligopeptide," according to claim 1. Claims 2-4 are anticipated because the supplement included a carbohydrate; claim 5 because L-histidine was included; claim 7 because the carbohydrate is an insulin promoter; claim 10 because the supplement was a liquid; and claims 13 and 14 because the recited consequences necessarily result in Gardner, and are thus inherent.

Claims 12, 17 and 19 of the '422 Patent are likewise anticipated by Gardner. Gardner discloses a human subject ingesting a 'dietary supplement' comprising 'beta-alanine that is not part of a dipeptide, polypeptide or oligopeptide' and which is not a natural or conventional food. Once ingested, the beta-alanine will necessarily be absorbed into the blood stream and from the blood stream into the subject's muscle tissue and this will inherently and necessarily increase beta-alanyl-histidine dipeptide synthesis in the muscle to avoid or delay fatigue. Thus Gardner anticipates claim 12 of the '422 Patent. Claim 17 is anticipated because the method of administration was by ingestion; claim 19 because the subject was a human being.

²⁰ Gardner, et al., Intestinal Absorption of the Intact Peptide Carnosine in Man, and Comparison with Intestinal Permeability to Lactulose, *Journal of Physiology* (1991), Vol. 439, p. 411-422 ("Gardner"). See p. 22 of Exhibit 3 and Exhibit L to Exhibit 3.

European Patent Publication No. 0 280 593

Claims 1, 2, 3, 4, 7, 11, 13 and 14 are anticipated under 35 U.S. C. § 102(b) by EP No. 0 280 593 (“EP ‘593”) (1991).²¹ EP ‘593 discloses a human dietary supplement containing beta-alanine that is not part of a dipeptide, polypeptide or oligopeptide, and which is not a natural or conventional food according to claim 1 of the ‘381 Patent. While the supplement disclosed in EP ‘593 was used for cancer therapy, the ultimate objectives of ingesting the composition are not recited in claim 1 nor would their recitation be a proper limitation for a composition claim.²² The claimed composition is anticipated.

EP ‘593 thus discloses a human dietary supplement comprising beta-alanine that is not part of a dipeptide, polypeptide or oligopeptide, and, not a natural or conventional food, according to claim 1 of the ‘381 Patent. Claims 2-4 of the ‘381 patent are anticipated because the disclosed compositions contain glucose, a simple carbohydrate; claim 7 because glucose is an insulin stimulating agent; claim 11 because the disclosed supplement is in solid form; and claims 13 and 14 because they merely recite the natural consequences of ingesting the supplement.

Claims 12, 17 and 19 of the ‘422 Patent are also anticipated by EP ‘593. The step of ingesting the dietary supplement anticipates claim 12. Once ingested, the physiological process described above in connection with Asatoor and Gardner will take place and this will necessarily increase beta-alanyl-histidine dipeptide synthesis in the muscle tissue and avoid or delay fatigue. The step of ingesting the dietary supplement and the results which necessarily flow from ingesting anticipate claim 12. Claim 17 is anticipated because the method of administration was by ingestion; and claim 19 because the test subjects were human beings.

²¹ European Patent Office Publication No. 0 280 593 B1, June 12, 1991 (“EP ‘593”), including both the text in French and an English language translation provided by the EPO. See p. 20-21 of Exhibit 3 and Exhibit K to Exhibit 3.

²² In NAI’s Reply to Woodbolt’s Opposition to its Motion for Preliminary Injunction on the ‘422 Patent (D.I. 43) NAI acknowledged that EP ‘593 is “drawn to composition of beta alanine”.

U.S. Patent No. Re. 30,370 to Pittet

Claims 1, 11, 13 and 14 of the '381 Patent are anticipated by Re. 30,370 issued August 12, 1980.²³ Re. 30,370 discloses a food supplement containing beta-alanine, which is not a natural or conventional food form. (See col. 12, lines 19-39) Because the food supplement contains beta-alanine, it will necessarily avoid or delay the onset of muscular fatigue.

U.S. Patent No. 3,966,988 to Wilson

Claims 1, 11, 13 and 14 of the '381 Patent are anticipated by U.S. Patent No. 3,966,988 issued June 29, 1976.²⁴ U.S. Patent No. 3,966,988 discloses a chicken flavored composition in solid form containing beta-alanine used in a foodstuff supplement, which supplement is not in a natural or conventional food form. (See col. 1, lines 9-27, and col. 6, lines 25-68) Because the food supplement contains beta-alanine, it will necessarily avoid or delay the onset of muscular fatigue.

D. All the Claims of the '381 and '422 Patents are Anticipated by NAI's Own U.S. Patent No. 5,965,596**1. NAI's U.S. Patent No. 5,965,596 is Prior Art To the '381 and '422 Patents**

The '381 and '422 Patents are, respectively, the Seventh and Eighth Patents in a family of related patents claiming compositions containing beta-alanine and methods for using those compositions. Both the '381 and '422 Patents contain purported claims to the U.S. priority of the earliest application of the family, filed on August 12, 1997, under 35 U.S.C. § 120. The purported claims seek to link the '381 Patent application and the '422 Patent application with earlier-filed applications and link those earlier applications with still earlier applications back to

²³ U.S. Patent No. Re. 30,370, Exhibit 11, relevant portions excerpted and set forth separately, Exhibit 13.

²⁴ U.S. Patent No. 3,966,988, Exhibit 11, relevant portions excerpted and set forth separately, Exhibit 14.

1997. NAI's attempted goal was to have *an effective filing date* for each of the '381 and '422 Patents of August 12, 1997, thereby cutting off all prior art published after that date.

To form each link in the chain of priority three conditions must be met: 1) the invention disclosed in the later application must be *disclosed* in the earlier application; 2) the later and earlier applications must be *copending*; and 3) the later application must *specifically refer* to the earlier applications.²⁵

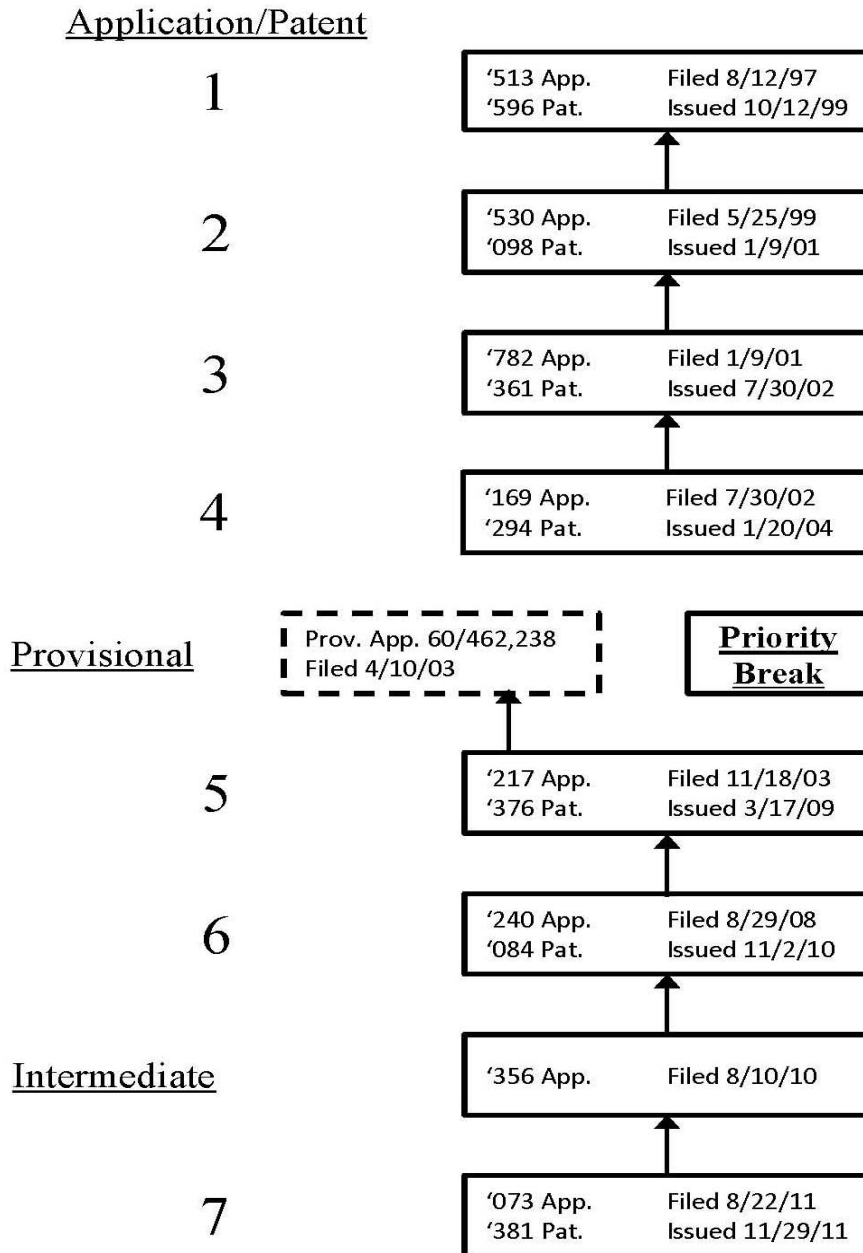
NAI filed each of the First-Fourth Applications in the series and met these three criteria. When the Fifth Application was filed, it too met these three criteria. However, during the pendency of the Fifth Application, NAI amended the priority claim, and *intentionally* and *deliberately* cancelled the specific reference to the Fourth Application and its three predecessors. NAI thereby terminated the claim of the Fifth Application to the 1997 filing date of the First Application.

This disclaimer in the Fifth Application not only affected the Fifth Application, it also foreclosed the possibility of NAI's assertion of a claim to priority in any subsequent applications - including the Seventh Patent (the '381 Patent) and the Eighth Patent (the '422 Patent) - to any date earlier than the effective filing date of the Fifth Application, April 10, 2003. Stated differently, once the priority of the First-Fourth Applications was disclaimed by breaking the link between the Fifth and Fourth Applications, the Fifth, Sixth, Seventh and Eighth Applications could no longer claim an effective filing date earlier than April 10, 2003.

The break in the chain can be seen in the following chart which depicts the events described above in the First – Seventh Applications.²⁶

²⁵ NAI acknowledges that three conditions are required in its Reply in Support of Its Motion for a Preliminary Injunction filed July 18, 2012 (D.I. 43).

²⁶ This chart appears at p. 6 of the '381 Request, Exhibit 3. A similar chart relating to the '422 Patent appears at p. 7 of the '422 Request, Exhibit 5.

Chain of Priority '381 Patent

The vertical arrows indicate entitlement to priority of one application to its immediate predecessor, and the absence of a vertical arrow indicates that an application is not entitled to a claim of priority to its immediate predecessor. There is a “PRIORITY BREAK” between Application Five and Application Four, indicating that Application Five is not entitled to claim the filing date benefit to Application Four or earlier applications.

As a result of NAI's disclaimer, the priority claim of the Fifth Patent states:

**“Domestic Priority data as claimed by applicant.
This appln claims benefit of 60/462,238 04/10/2003”²⁷**

The priority claim makes no reference whatsoever to the Fourth...First Applications.

Notwithstanding their *intentional disclaimer* of the priority claim between the Fifth and Fourth Patents, when NAI filed the applications which issued as the '381 and '422 Patents, NAI stated that these applications claimed priority back through the Fifth Application to the Fourth and earlier Applications to August 12, 1997.²⁸ These statements were untrue. They were misrepresentations to the USPTO. They were misrepresentations upon which the examiner relied in determining the *effective filing date* of those applications. The *effective filing date* should have been April 10, 2003, not August 12, 1997.

Because the '381 Patent and '422 patent are not entitled to an effective filing date earlier than April 10, 2003, patents and publications (whether of a third party or NAI) with a date earlier than April 10, 2003 are prior art to the '381 and '422 Patents. NAI's own '596 Patent, issued in 1999, is thus prior art under 35 U.S.C. §102(b). The '596 Patent discloses every claim feature of the alleged inventions claimed in the '381 and '422 Patents.²⁹

As a result of NAI's misrepresentations to the USPTO in the respective claims to priority, both the '381 Patent and the '422 Patent issued with false claims to priority on their cover pages. The claim to priority on the face of the '381 Patent is representative.

Continuation of application No. 12/806,356, filed on Aug. 10, 2010 [Intermediate Application],
which is a continuation of application No. 12/231,240, filed Aug. 29, 2008, now Pat. No. 7,825,084 [Sixth Application],

²⁷ See Exhibit F to '381 Request, Exhibit 3.

²⁸ Amendments in the '381 Patent application, Exhibit 7, p. 2 and Amendment, June 16, 2011 in Application Ser. No. 12/806,356 for the '422 Patent, Exhibit 15, show NAI's false priority claims.

²⁹ The '381 Request Exhibit 3, p. 16-18, and the '422 Request, Exhibit 5, p. 14-17 provide claim charts showing how each element of claims 1-14 of the '381 Patent and claims 12-17 of the '422 Patent is disclosed in the '596 Patent.

which is a continuation of application No. 10/717,217, filed on Nov. 18, 2003, now Pat. No. 7,504,376, [Fifth Application] and a continuation-in-part of application No. 10/209,169, filed on Jul. 30, 2002, now Pat. No. 6,680,294 [Fourth Application],

which is a continuation of application No. 09/757,782, filed on Jan. 9, 2001, now Pat. No. 6,426,361 [Third Application], which is a continuation of application No. 09/318,530, filed on May 25, 1999, now Pat. No. 6,172,098 [Second Application], which is a division of application No. 08/909,513, filed on August 12, 1997, now Pat. No. 5,965,596 [First Application].

Provisional application No. 60/462,238, filed on Apr. 10, 2003 [Provisional Application].³⁰

The claim is false because it purports to link the ‘381 Application all the way back to the First Application filed in August 12, 1997 which issued as the ‘596 Patent. As discussed above, because of the intentional disclaimer of priority in the Fifth Application, no later application linked to the Fifth Application could claim an effective filing date earlier than April 10, 2003.

The claim to priority on the face of the ‘381 Patent is also false because it misstates the relationship between applications in the chain. And, it fails for not one but *two* of the three criteria for creating links between later and earlier filed applications.

First, the claim recites that the Sixth Application is a *continuation-in-part* of the Fourth Application. That is not true because the Fourth Application issued as U.S. Pat. No. 6,680,294 on January 20, 2004 and the Sixth Application was not filed until August 29, 2008, *more than four years later*. Hence, the “**copendency**” requirement prong of the test is not met.

Second, the Fifth Application does not **specifically refer** to the Fourth Application. The claim therefore fails the “specific reference” prong of the test which requires *each* later-filed application to contain a *specific reference* to an earlier-filed copending application.

³⁰ The identification of each Application has been added in brackets “[]” for reference herein. Underlining and bolding has been added for emphasis.

The claim to priority on the face of the '381 Patent is a misrepresentation of the effective filing date of the '381 Patent to the public. As such the '381 Patent fails to give proper notice of critical priority facts to the public.³¹

NAI will likely argue that the “copendency” and “specific reference” criteria were met in the Fifth Application from the filing date of the Fifth Application until the priority disclaimer (September 2, 2008), because the Sixth Application was filed before the priority disclaimer, and the Sixth Application thereby secured its own and its successors' ('381 and '422 Patents) priorities before the disclaimer was filed.³² NAI's cooked-up theory posits that the Fifth Application can have *two* different claims to priority, one claim for the Fifth Application's patent claims, and another different priority claim for subsequent applications. The USPTO, in the '381 Reexam Order, implicitly rejected NAI's position by ruling that the priority disclaimer in the Fifth Application applied also to the Seventh Application (for the '381 Patent).

The wording of the claim to priority which NAI filed in the '381 Application (Exhibit 7) flies in the face of NAI's theory because it states that the Fifth Application is a continuation-in-part of the Fourth Application. The accepted expression for specific references between a later - and an earlier- filed, copending application is as follows: “...the later application is a continuation...of the earlier application.”³³ While the Fifth Application, when it was filed and up to the time the disclaimer was filed, correctly stated that it is a continuation-in-part of the Fourth Application, when the '381 Application was filed some three years later, that recitation of “is” was no longer true. The Fifth Application issued March 12, 2009 with the priority claim

³¹ See *Simmons, Inc. v. Bombardier, Inc.*, 328 F. Supp. 2d. 1188, 1201 (D.Utah, 2004)(“However, it seems clear that not only is it appropriate to require a statement of some relationship in an application, but a statement of the *correct* relationship. Parties viewing a patent and taking legal risks based upon it are entitled to know the correct relationship of the application.”)

³² NAI's Reply to Woodbolt Opposition to NAI Motion for Preliminary Injunction, (D.I. 43)

³³ Manual of Patent Examining Procedure (MPEP), §201.11 II A, entitled “Reference to Prior Nonprovisional Applications.”

quoted above making no reference whatsoever to the Fourth Application. The Fifth Application was a continuation-in-part of the Fourth Application until the disclaimer was filed on September 2, 2008. But, after that disclaimer it was simply untrue to state that it still is a continuation-in-part.

Because the effective filing date of the '381 and '422 Patents is no earlier than April 10, 2003, the '596 Patent is prior art under 35 U.S.C. § 102(b) to both the '381 and '422 Patents.

2. The '596 Patent Invalidates the '381 and '422 Patents

Each and every claim of both the '381 and '422 Patents is disclosed in the '596 Patent.³⁴ Because all of the features of these claims are disclosed in the '596 Patent, the '381 and '422 Patents are invalid as anticipated by the '596 Patent. The '381 Office Action has ruled likewise for the '381 Patent claims in the '381 reexamination.

E. Claims of the '381 and '422 Patents Are Invalid Because They Are Obvious From the Prior Art

As discussed above, even if a claim is novel because it is not disclosed by a single prior art reference, to be patentable it must also be unobvious in view of the prior art. Under the *KSR* case, it would be obvious for persons of ordinary skill in the art to consider combining prior art elements in the same field of endeavor according to known elements to yield predictable results.

In the '381 Request, Woodbolt presented several combinations of references which show the claims of the '381 and '422 Patents to be obvious. These combinations of references were not considered by the USPTO when examining the '381 and '422 Patents.³⁵ Several of these

³⁴ A claim chart showing how the '596 Patent anticipates each claim of the '381 Patent is in the '381 Request, Exhibit 3, at p. 16-18. A similar chart with respect to claims 12-19 of the '422 Patent appears at p. 14-17 of the '422 Request, Exhibit 5.

³⁵ See '381 Request, Exhibit 3, p. 25-34 and '422 Request, Exhibit 5, p. 26-33.

bases were adopted by the USPTO in the '381 Reexam Order and are the bases for rejection of the claims in the Office Action.³⁶

One such representative basis is that certain claims were obvious based on the combination of the Setra European patent with Asatoor (discussed above).³⁷ Ground #7 in the '381 Office Action states:

Claims 1-5, 7-8 and 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Setra (EP '787) in view of Asatoor.

Setra discloses pharmaceutical, dietetic or veterinary compositions containing carnosine or peptides related thereto as the active ingredient (see page 2 lines 28-34). In particular, Setra discusses the known beneficial properties of these compositions when they are ingested. The compositions are said to secure the known benefits of carnosine (a dipeptide, namely β -alanyl-L-histidine, formed from the amino acids β -alanine and L-histidine) (see page 2, lines 4-5), including carnosine's ability to prevent uncontrolled proton release in the cell and thus a drop in cellular pH and thus prevent "metabolic acidosis" and its consequences, i.e. muscular fatigue and weakness (see page 2, lines 3-13). Example 1 discloses compositions comprising Carnosine, Histidine, Carnitine, Creatine, Glucose and Flavoring agents (see page 2).

Setra does not teach a composition comprising beta-alanine. However, Asatoor in the same field of endeavor discloses a dietary composition (a mixture) comprising beta-alanine and L-histidine (free amino acids) (see the Abstract and Methods). Asatoor discloses that the absorption of the free amino acids (beta-alanine or L-histidine) is significantly more rapid than the di-peptide (carnosine) (see pages 250 and 252). Thus it would have been obvious to a person of ordinary skill in the art at the time of the invention to include beta-alanine, a known non-essential amino acid and a precursor of carnosine, alone or together with L-histidine in the compositions of Setra because Asatoor teaches the rapid intake of free amino acid beta-alanine.

Regarding claims 2-4, the compositions of Setra include glucose (a simple carbohydrate) (see Example 1). Regarding claim 5, both Setra and Asatoor teach the compositions additionally comprising L-histidine. Regarding claim 7, glucose is the most common insulin stimulating agent. Regarding claim 8, the composition of Setra comprises creatine. Regarding claims 10-12, Setra teaches that the compositions are either liquid, solid form or a suspension. Claims 13-14 recite the inherent function of the composition. The composition disclosed in Setra and Asatoor will have those inherent functions falling within the scope of the present claims.³⁸ (emphasis added)

³⁶ See '381 Reexam Order p. 11-16 and '381 Office Action p. 11-15 (Exhibit 4).

³⁷ Setra, Exhibit 2 to '381 Request, Exhibit 3.

³⁸ '381 Office Action, p. 12.

The examiner in the '381 reexam recognized that Setra and Asatoor were working in the same field of endeavor, that both described dietary compositions, that Asatoor had found that beta-alanine, as a free amino acid, was absorbed more rapidly than the dipeptide, carnosine, and, that therefore it would have been obvious to include beta-alanine, the known precursor of carnosine, in the composition of Setra. In so concluding, the examiner followed the argument Woodbolt set forth in the '381 Request.³⁹

In making the rejection the examiner was following two of the three obviousness rationales of KSR, combining prior elements in the prior art which when combined yield predictable results and following suggestions in the prior art to combine the reference teachings to arrive at the claimed invention.

In its '381 Request, p. 28, Woodbolt noted that Setra stated that its compositions could also include other ingredients such as ... non-essential amino acids ... One skilled in the art reading Setra would thus be highly motivated to choose beta-alanine, a well-known, non-essential amino acid [studied by Asatoor] from a very finite (short) list of other possible ingredients, thereby meeting the other obviousness rationale of KSR ("obvious to try").

Grounds Nos. 8, 9, 10, 11 and 12 set forth additional bases for the rejection of all of the claims of the '381 Patent under 35 U.S.C. § 103 and are incorporated herein.⁴⁰

³⁹ '381 Request, Exhibit 3, pages 27-28

⁴⁰ '381 Office Action, Exhibit 4, pages 12-15

Conclusion

In view of the foregoing, Woodbolt respectfully submits that claims 1-14 of U.S. Patent No. 8,067,381 and claims 12-17 of U.S. Patent No. 8,129,422 are invalid for failing to comply with 35 U.S.C. §§ 102 and 103, and requests an order finding all of the claims of these two patents invalid.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that a true and complete copy of *DEFENDANT WOODBOLT'S MOTION FOR SUMMARY JUDGMENT OF PATENT INVALIDITY OF PLAINTIFF'S U.S. PATENTS NOS. 8,067,381 AND 8,129,422* was filed by ECF on August 3, 2012, which constitutes service on all parties.

Jayne S. Partridge